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PATIENT-FOCUSED, EVIDENCE-BASED ADDICTION TREATMENT

Hepatitis C Virus from Screening to Cure

Dr. Amitkumar Patel
Medical Director, BrightView

MEET TODAY'S SPEAKER

Dr. Amitkumar Patel

Medical Director

Dr. Amitkumar Patel has been with BrightView for the past 6 years as the Medical Director. After graduating with a degree in Electrical Engineering from the University of Maryland, Dr. Patel pursued his medical degree and finished his residency at Jewish Hospital in Cincinnati. He worked in a hospital setting for many years and joined BrightView in 2017. Dr. Patel has been named one of "Cincinnati's Top Doctor's In Addiction Medicine" of 2022 as well as Internal Medicine for 2020 and 2021. Joining BrightView has allowed Dr. Patel to work with an incredible team of likeminded individuals on a patient centered approach to help in the fight against addiction. He has been privileged to observe many positive outcomes in several of his patient's lives thus far and hopes to continue to witness many more.

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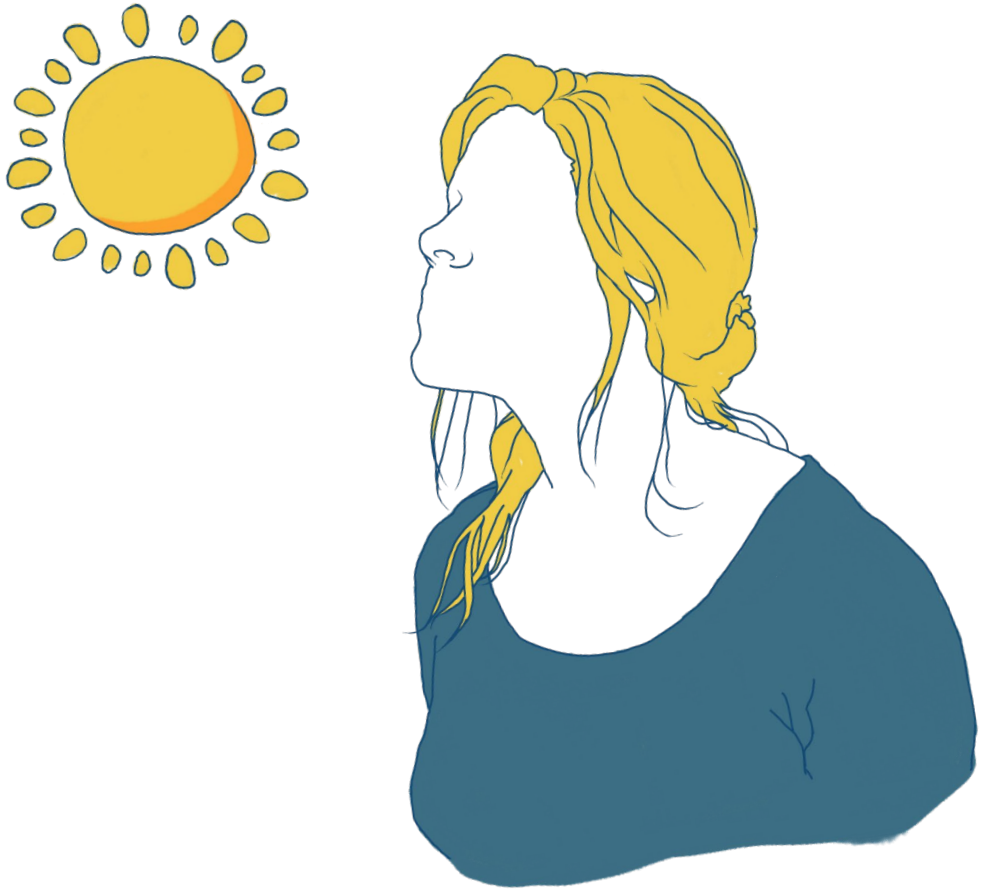
AGENDA

- Hepatitis C overview
- Acute vs Chronic
- Prevalence of Hepatitis C
- Risk of disease progression
- Treatment factors
- Treatment options
- Q&A



WHAT IS HEPATITIS C?
HOW IS IT TRANSMITTED?

Inflammation of the liver caused by the Hepatitis C virus, is preventable and curable.

How is it spread? - infected blood

- IVDU accounts for the majority of new HCV infections (approximately 70%)
- Childbirth - Approximately 6% of infants born to infected mothers will get hepatitis C.
- Tattoo, piercing equipment (not sanitized)
- Rarely through sexual activity, more often among men who have sex with men.
- Rarely transmitted through blood transfusions due to screening blood products.

Symptoms can include:

- Fever
- Extreme fatigue
- Abdominal pain
- Nausea
- Diarrhea
- Anorexia
- Weight loss
- Dark urine
- Grey-colored stool
- Joint pain
- Yellow skin and eyes

Extrahepatic manifestations:

- Mixed cryoglobulinemia
- Lymphoma
- Diabetes
- Dermatologic and autoimmune

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ACUTE VERSUS CHRONIC

Acute	Chronic
Often, people with an acute Hepatitis C infection often do not know they have the virus and therefore unintentionally do not get treated. (Symptoms in acute infection are rare)	Defined as having infection for 6 months or longer Many people already have chronic Hepatitis C when they're first diagnosed because they were unknowingly infected with the virus many years ago.
However, if a person realizes that they may have been exposed to the virus – like a nurse who gets a needle stick – an acute Hepatitis C infection can be identified early, and medication may be recommended.	In the United States, chronic HCV is the most common cause of chronic liver disease Increased risk of hepatocellular carcinoma and death.
Usually self-limited.	It is the most common reason for liver transplantation in the United States.

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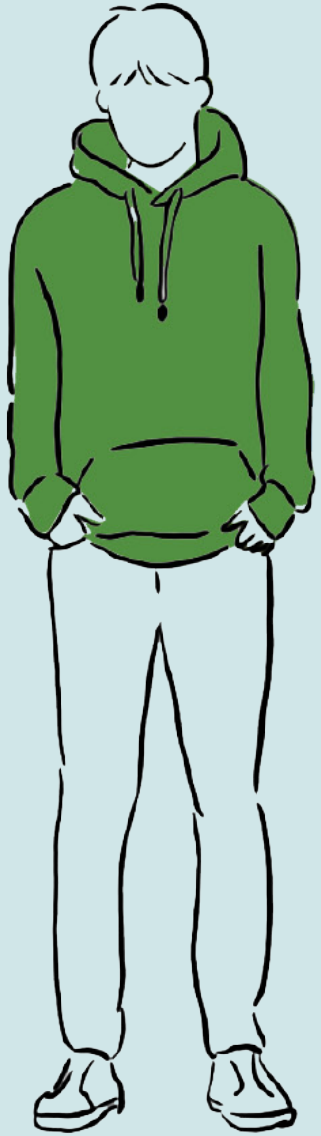
PREVALENCE OF HEPATITIS C



- About 50,000 new cases annually in the United States, 3x more than Hepatitis B
- Since acute symptomatic instances are rare, about 75% of those exposed to the virus will go on to develop chronic Hepatitis C
- Less than half of people who are infected with the Hepatitis C virus clear it from their bodies without treatment.
- About 20-30% of chronic Hepatitis C infected patients will go on to develop cirrhosis

In the USA, the age-adjusted mortality rate among patients with HCV is higher than those with HIV, and there are roughly 10-15,000 deaths per year in the USA due to chronic HCV infection, and more than 400,000 deaths yearly worldwide. (https://hivhep.org/)

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PREVALENCE/SCREENING AMONGST PWID

- People who inject drugs (PWID) are more likely to be infected with Hep C, less likely to receive treatment for it and more likely to have recurrent infections
- Although a large proportion of people who inject drugs who have been diagnosed with Hepatitis C express willingness to undergo treatment, a disproportionately low number have received antiviral therapy

What is being done?

- In 2019, new guidelines/recommendations were set in place for one-time screenings for adults aged 18-79, set in place by the CDC, AASLD, IDSA, and USPSTF

- The reality is that 45% of those infected with HCV do not recall or report a classic risk factor, so universal screening is a huge positive step.

Screening: Per the AASLD-IDSA (American Association for the Study of Liver Diseases and Infectious Diseases Society of America) HCV Guidance, recent or active injection-drug use or alcohol use should not be a contraindication to getting HCV treatment.

Therefore, pretreatment screening for illicit drug or alcohol use should be discontinued.

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BARRIERS TO TREATMENT/REINFECTION

Patients experiencing:

- Homelessness
- Poverty
- Addiction
- Mental health conditions
- Poor relationships/trust issues with healthcare providers
- Lack of insurance
- Unpredictable follow-through

Providers with:

- A lack of training in substance use disorder
- Inexperience with viral infections
- Unrealistic expectations (patients won't follow up, dishonest)
- Prejudicial attitude towards PWUD or PWID

This can lead to frustration and resentment towards patients, leading to the patients not trusting healthcare systems and providers to have their best interest at heart, leading to a cycle of avoiding seeking treatment altogether, and/or not disclosing truthful information to healthcare providers, and/or not showing up for follow up appointments, etc.

Multiple studies have shown significant risk of HCV reinfection in persons cured with HCV therapy, who are using drugs

Emphasis on persons with past or active injection-drug use to be counseled on the risk of becoming reinfected with HCV after achieving an SVR.

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MODELS OF CARE

- Primary/specialized care
- Facility based treatment
- Community based clinics
- Specialized hospital-based clinics
- Inpatient and outpatient addiction treatment centers
  - Treatment centers that provide wrap around services
    - Addressing biological, psychological, and social elements to a person's addiction

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TREATMENT FACTORS & DIRECT ACTING ANTIVIRAL (DAA)

Treatment for Hepatitis C depends on several factors, including:

- Presence of a **viral load,** although poor correlation with severity
- The **genotype** or strain of Hepatitis C
- If the patient has **cirrhosis**
- What other health conditions the patient has – HIV, Hep B, DM, alcohol
- Patient's response to any previous treatments for Hepatitis C

Early intervention and education is key

- Up until just a few years ago, people living with Hepatitis C only had two medication options:
  - pegylated interferon
  - ribavirin
- Now, there are several medication options including:
  - protease inhibitors
  - polymerase inhibitors

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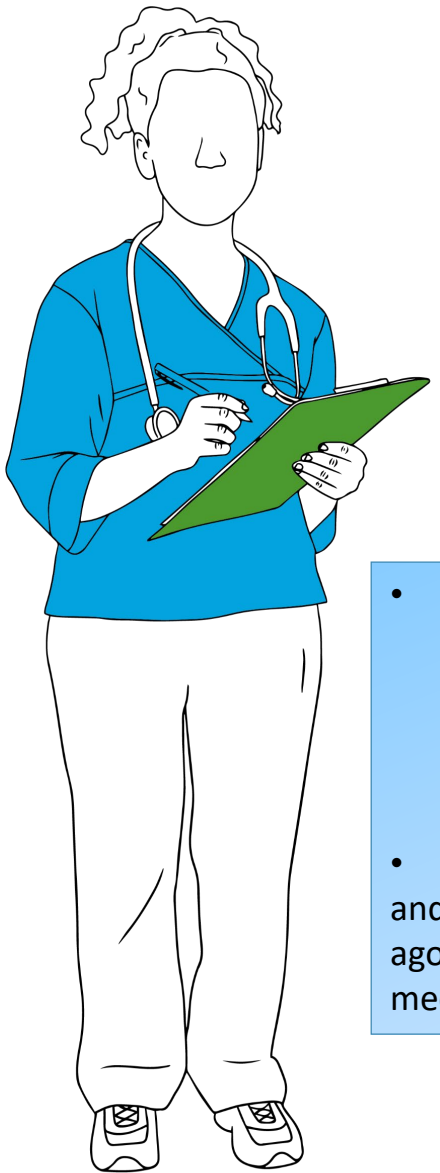
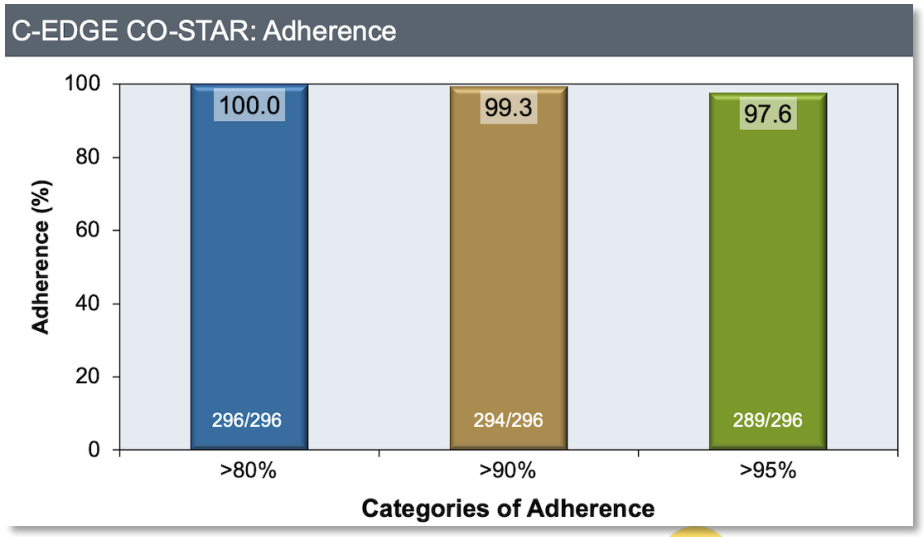
TREATMENT OPTIONS: DAA



- **Medications targeted at specific steps within the HCV life cycle.**
  - molecules that target specific nonstructural proteins of the virus and results in disruption of viral replication and infection.
  - There are four classes of DAAs
    - Defined by their mechanism of action and therapeutic target

- **Several recent studies, based on DAA regimens, have concluded that increasing access to HCV treatment in PWUD would have a major impact in reducing HCV incidence and prevalence in this patient population.**
  - Impact would be larger in the setting of increased access to sterile injection equipment and opioid agonist maintenance services.
    - Dispensing DAA therapy within a program that provides MOUDs increases the likelihood of PWUD engagement in HCV treatment

- Persons with OUD who receive opioid agonist maintenance therapy (e.g., methadone, buprenorphine, or buprenorphine-naloxone) during HCV treatment have excellent rates of adherence, treatment completion, and sustained virologic response (SVR) rates, all comparable to results of other study participants.
- Importantly, MOUDs do not compromise HCV treatment outcomes and there are no known clinically significant interactions between opioid agonist therapies or naltrexone and currently approved DAA medications.



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HCV SIMPLIFIED TREATMENT

For treatment naïve persons without cirrhosis:

- A simplified treatment algorithm to provide guidance to non-HCV specialists.
  - Global elimination of HCV infection will require the engagement of frontline health care providers to increase the capacity to treat patients.
- Patient eligible
  - Adults with chronic Hepatitis C (any genotype) who do not have cirrhosis and have not previously received hepatitis C treatment
- Patients not eligible:
  - Patients who have any of the following characteristics:
    - ✓ Prior hepatitis C treatment
    - ✓ Cirrhosis
    - ✓ HIV and/or HBsAg positive
    - ✓ Current pregnancy
    - ✓ Known or suspected hepatocellular carcinoma
    - ✓ Prior liver transplantation

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HCV SIMPLIFIED TREATMENT CONTINUED

Calculate FIB-4 score

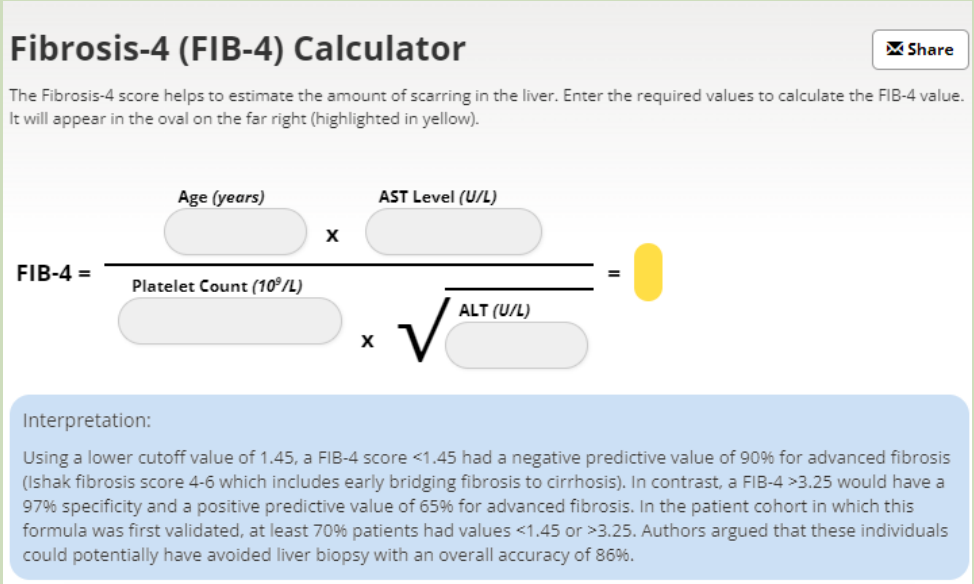
- **Cirrhosis assessment:** Liver biopsy is not required. A patient is presumed to have cirrhosis if they have a FIB-4 score >3.25 **or** confirmation from a prior test

- **Medication reconciliation:** Record current medications, including over-the-counter drugs and herbal/dietary supplements.

- **Potential drug-drug interaction assessment:** Drug-drug interactions can be assessed using the AASLD/IDSA guidance or the University of Liverpool drug interaction checker.

- **Education:** proper administration of medications, adherence, and prevention of reinfection.

- **Pretreatment laboratory testing:**
  - *Within 6 months of initiating treatment:* CBC, LFT, eGFR
  - *Any time prior to starting antiviral therapy:* Quant HCV RNA, HIV, HBS
  - *Before initiating antiviral therapy*:
    - Serum pregnancy testing and counseling about pregnancy risks of HCV medication should be offered to women of childbearing age.



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HCV SIMPLIFIED TREATMENT CONTINUED

Recommended treatment

- Glecaprevir (300 mg) / pibrentasvir (120 mg) (Mavyret) to be taken with food for a duration of 8 weeks
- Sofosbuvir (400 mg) / velpatasvir (100 mg) (Epclusa) for a duration of 12 weeks

On treatment monitoring

- Monitoring for hypoglycemia is recommended in diabetic patients taking diabetes regimen.
- Monitoring INR for subtherapeutic anticoagulation is recommended for patients on warfarin.
- No laboratory monitoring is required for other patients.

Post treatment

- Assessment of quantitative HCV RNA and a hepatic function panel are recommended 12 weeks or later following completion of therapy to confirm HCV RNA is undetectable (virologic cure) and transaminase normalization.
- Assessment for other causes of liver disease is recommended for patients with elevated transaminase levels after achieving SVR.

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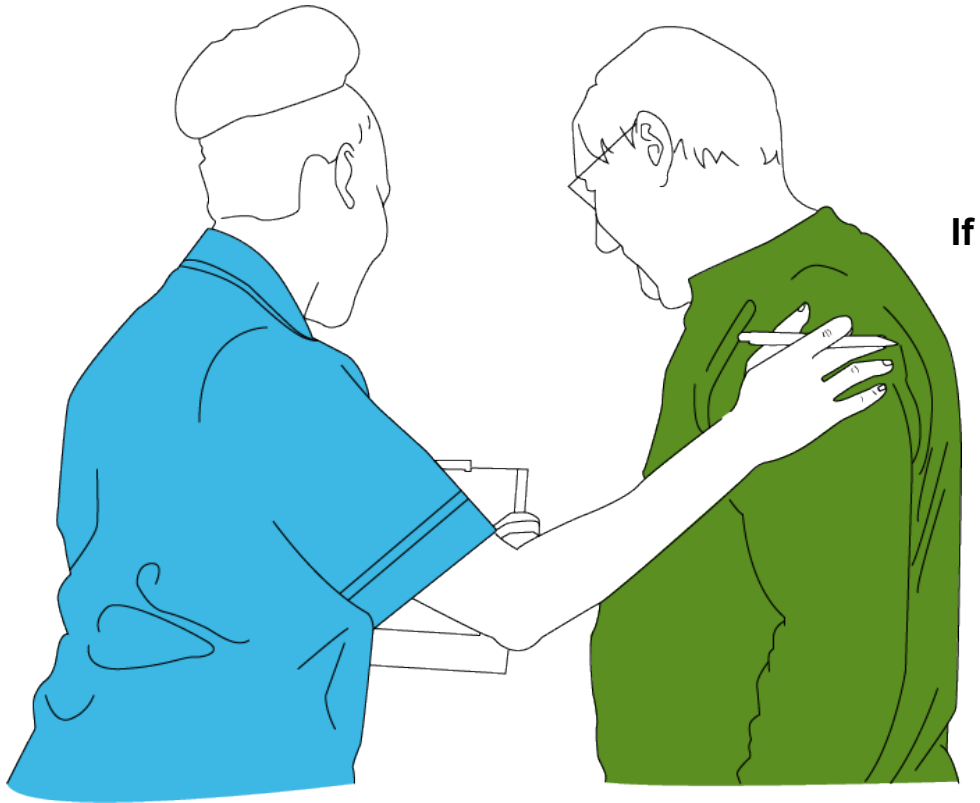
HCV SIMPLIFIED TREATMENT CONTINUED



If achieving SVR:

- No liver-related follow-up is recommended for noncirrhotic patients who achieve SVR.
- Patients with ongoing risk for HCV infection (e.g., intravenous drug use or engaging in unprotected sex) should be counseled about risk reduction and tested for HCV RNA annually and whenever they develop elevated ALT, AST, or bilirubin.

- Advise patients to avoid excess alcohol use.

If not achieving SVR:

- Patients in whom initial HCV treatment fails to achieve cure (SVR) should be evaluated for retreatment by a specialist
- Until retreatment occurs, assessment for disease progression every 6 to 12 months with a hepatic function panel, CBC, and INR is recommended.
- Advise patients to avoid excess alcohol use.

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THE KEY: HARM REDUCTION

- Increased education and awareness to vulnerable populations
- Increased screening opportunities
- More outreach/boots on the ground
- More support from social services, legislation, communities
- Less stigma attached to the actual virus (no one deserves this)

All of these components work together towards reducing transmission which is **harm reduction.**

QUESTIONS?

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REFERENCES

- **hcvguidelines.org**
- **hepatitisc.uw.edu**
- hivhep.org
- liverfoundation.org
- Pubmed.ncbi.nlm.nih.gov
- UpToDate

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